

PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 445/04392	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/IL2005/000304	International filing date (day/month/year) 17.03.2005	Priority date (day/month/year) 18.03.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61F2/00			
Applicant CONTIPI LTD. et Al.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 10 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 4 sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input checked="" type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 18.01.2006	Date of completion of this report 06.07.2006
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Mary, C Telephone No. +31 70 340-4409



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL2005/000304

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
 - the international application in the language in which it was filed
 - a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3(a) and 23.1(b))
 - publication of the international application (under Rule 12.4(a))
 - international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-19 as originally filed

Claims, Numbers

1-31 filed with telefax on 22.06.2006

Drawings, Sheets

1/19-19/19 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/L2005/000304

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,
 claims Nos. 26-29

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no international search report has been established for the said claims Nos. 26-29

a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/L2005/000304

Box No. IV Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
 - restricted the claims.
 - paid additional fees.
 - paid additional fees under protest and, where applicable, the protest fee.
 - paid additional fees under protest but the applicable protest fee was not paid.
 - neither restricted the claims nor paid additional fees.
2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
 - complied with.
 - not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
 - all parts.
 - the parts relating to claims Nos. 1-25, 30-31 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 1-25, 30-31

No: Claims

Inventive step (IS) Yes: Claims 1-25, 30-31

No: Claims

Industrial applicability (IA) Yes: Claims 1-25, 30-31

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2005/000304

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet



**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
PCT/IL2005/000304

Re Item III.

Rule 39.1(iv) and Rule 67.1 (iv) PCT - Method for treatment of the human or animal body by therapy: Claims 26-29 disclose a method of using an apparatus for the treatment of urinary incontinence.

Re Item IV.

The separate inventions/groups of inventions are:

- Claims 1-25: an apparatus for treating urinary incontinence.
- Claims 30-31 an apparatus for inserting a vaginal device

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons: the document US5785640 cited in our search report discloses an apparatus for treating urinary incontinence. Beyond this prior art, the special technical features (in the meaning of Rule 13.2 of the P.C.T) left in the independant claims 1, 16, 23, 30 of the application are:

- In independant claims 1, 16, 23 : none.
- In independant claim 30: an apparatus for inserting a vaginal device.

No same or correspondent special technical feature can be found between claims 1, 16, 23 and claim 30. There is therefore no technical relationship involving same or corresponding special technical features between claims 1, 16, 23 and claim 30.

The inventions defined in the above-mentioned claims are not linked by a common inventive concept.

Re Item V.

- 1 Reference is made to the following documents:

D1 : US 5 785 640 A (KRESCH ET AL) 28 July 1998 (1998-07-28)

D2 : US 5 483 976 A (MCLAUGHLIN ET AL) 16 January 1996 (1996-01-16)

D6: US5788664 (SCALISE) 4 August 1998 (1998-08-04)

This document was not cited in the international search report. A copy of the document is appended hereto.

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
PCT/IL2005/000304

2 INDEPENDENT CLAIM 1

Document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document) (see column 4, line 40 to column 8, line 59): an apparatus (4) for treating urinary incontinence, comprising: a node; a support section (6, 8) adapted for providing urethral support attached to said node; and an anchoring section (10, 12) adapted for resisting movement of said apparatus attached to said node; wherein said node is no longer than 30% of the entire length of said apparatus comprising said node, support section and said anchoring section together.

The subject-matter of claim 1 thus differs from this disclosure in that the apparatus is arranged around a central axis and that the node is located on the central axis. Therefore the subject-matter of claim 1 is new and meets the requirements of Art.33(2)PCT.

The specific geometry of the device disclosed in claim 1 allows a smaller apparatus, more flexible and more comfortable. None of the available prior art documents suggests an apparatus arranged around a central axis with a node located on the central axis.

Therefore claim 1 involves an inventive step and meets the requirements of Art.33(3)PCT.

The device disclosed in claim 1 is industrially manufacturable and therefore the claim meets the requirements of Art. 33(4)PCT.

Claims 2 to 15 refer to further embodiments of the device of claim 1 and in view of that meet the requirements of Art. 33(2), (3), and (4) PCT as well.

3 INDEPENDENT CLAIM 16

Document D2 is regarded as being the closest prior art to the subject-matter of claim 16, and discloses (the references in parentheses applying to this document) : an apparatus (10) for treating urinary incontinence, comprising a support (4) section; and an extending insert (12) adapted to adjust the diameter of said support section.

The subject-matter of claim 16 thus differs from this disclosure in that the device is

adapted for providing urethral support; that the support section "uses a plurality of outwardly extending arms", and that the insert is adapted to increase the diameter of the support section "by outwardly urging the arms".

Therefore the subject-matter of claim 16 is new and meets the requirements of Art.33(2)PCT.

The device disclosed in D2 does not have arms per se but extensions and is an actuated urethral plug. The device disclosed in claim 1 allows, by supporting the urethra and not blocking it, to prevent incontinence while to urinate is still possible without having to remove the device. Moreover the device has a variable geometry and can be adapted to a specific anatomy. None of the available prior art documents suggests a combination of these specific technical features.

Therefore claim 16 involves an inventive step and meets the requirements of Art.33(3)PCT.

The device disclosed in claim 16 is industrially manufacturable and therefore the claim meets the requirements of Art. 33(4)PCT.

Claims 17 to 22 refer to further embodiments of the device of claim 16 and in view of that meet the requirements of Art. 33(2), (3), and (4) PCT as well.

4 INDEPENDENT CLAIM 23

The document D1 is regarded as being the closest prior art to the subject-matter of claim 23, and discloses (the references in parentheses applying to this document): an apparatus for treating urinary incontinence, comprising: a body (4) provided with a plurality of arms adapted for rendering urethral support for treating incontinence when inserted in a vagina; and a device displacer (128).

The subject-matter of claim 23 thus differs from this disclosure in that the device also comprises "an arm collapser" and that the device displacer is "coupled to the arm collapser which when pulled causes the arms to collapse and the apparatus to displace".

Therefore the subject-matter of claim 23 is new and meets the requirements of Art.33(2)PCT.

The arm collapser, linked to the device displacer allow to reduce the device's profile

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
PCT/IL2005/000304

within the vagina and an easier removal. None of the available prior art documents suggests a combination of these specific technical features. Therefore claim 23 involves an inventive step and meets the requirements of Art.33(3)PCT.

The device disclosed in claim 23 is industrially manufacturable and therefore the claim meets the requirements of Art. 33(4)PCT.

Claims 24 to 25 refer to further embodiments of the device of claim 23 and in view of that meet the requirements of Art. 33(2), (3), and (4) PCT as well.

5 INDEPENDENT CLAIM 30

The document D6 is regarded as being the closest prior art to the subject-matter of claim 30, and discloses (the references in parentheses applying to this document)(see column 3, lines 19-42): an apparatus (100) for inserting a vaginal device comprising an enclosure (102) for containing said vaginal device and a stopper (106), wherein said stopper (106) prevents over insertion and wherein said stopper is adjustably positioned on an exterior of said enclosure (102).

The subject-matter of claim 30 thus differs from this disclosure in that the apparatus is for inserting an "expanding and anchoring" vaginal device "having a preferred deployment location".

Therefore the subject-matter of claim 30 is new and meets the requirements of Art.33(2)PCT.

Document D6 discloses an applicator for a suppository (smaller element), not an expanding and anchoring device which has to be deployed at an appropriate depth within the vagina to render treatment effective. None of the available prior art documents suggests a combination of these specific technical features.

Therefore claim 30 involves an inventive step and meets the requirements of Art.33(3)PCT.

The device disclosed in claim 30 is industrially manufacturable and therefore the claim meets the requirements of Art. 33(4)PCT.

Claim 31 refers to further embodiments of the device of claim 30 and in view of that



**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/IL2005/000304

meets the requirements of Art. 33(2), (3), and (4) PCT as well.

Re Item VII.

6 Independent claims 1, 16, 23, 30 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

445/04392 A01A02

CLAIMS

1. An apparatus (100) arranged around a central axis (150) for treating urinary incontinence, comprising:
 - a non-organ supporting node (108) located on the central axis (150);
 - a support section (110) adapted for providing urethral support attached to said node;
 - and,
 - an anchoring section (106) adapted for resisting movement of said apparatus attached to said node;
 - wherein said node is no longer than 30% of the entire length of said apparatus comprising said node (108), support section (110) and said anchoring section (106) together.
2. An apparatus of claim 1 wherein said node (108) is no longer than 20% of the entire length of said apparatus for treating urinary incontinence.
3. An apparatus of claim 2 wherein said node (108) is no longer than 15% of the entire length of said apparatus for treating urinary incontinence.
4. An apparatus of any of claims 1-3 wherein said support section (110) is provided with at least 2 supporting arms (114).
5. An apparatus of any of claims 1-3 wherein said anchoring section (106) is provided with at least 2 anchoring arms (112).
6. An apparatus of any of claims 1-5 further comprising a cover (900).
7. An apparatus of claim 6, wherein said cover (900) substantially encapsulates said node (108), support section (110) and said anchoring section (106).
8. An apparatus of any of claims 1-7 wherein at least said support section (110) and said anchoring section (106) are flexible.



445/04392 A01A02

9. An apparatus of any of claims 1-7 wherein at least said node (108) is flexible.
10. An apparatus of any of claims 1-9 further comprising a device displacer (902).
11. An apparatus of claim 10 wherein said device displacer (902) is attached to said support section (110).
12. An apparatus of any of claims 4-11 further comprising support struts (320) interlinking said supporting arms (114).
13. An apparatus of any of claims 1-12 further comprising an applicator (1000) adapted to insert said apparatus into a vagina.
14. An apparatus of any of claims 1-13, wherein the apparatus (100) is symmetrically arranged around the central axis (150).
15. An apparatus of any of claims 1-14, wherein the length of the apparatus (100) is 50mm or less.
1416. An apparatus (400) for treating urinary incontinence, comprising:
a support section (410) adapted for providing urethral support using a plurality of outwardly extending arms (414); and
an extending insert (800) adapted to increase the diameter of said support section (410) by movement towards a cervixoutwardly urging the arms (414).
1517. An apparatus of claim 14-16 further comprising a node (408) an anchoring section (406) adapted for resisting movement of said apparatus.
1618. An apparatus of either of claims 14-16 or 15-17 further comprising a cover (900).
1719. An apparatus of claim 16-18 wherein said cover (900) substantially encapsulates said node (408), support section (410), said anchoring section (406) and extending insert (800).



| 445/04392 A01A02

| 1820. An apparatus of any of claims 1416-17-19 further comprising a device displacer
(902).

| 1921. An apparatus of claim 18-20 wherein said device displacer (902) is attached to said
support section (410).

| 2022. An apparatus of any of claims 1416-19-21 further comprising an applicator (1000)
adapted to insert said apparatus into a vagina.

| 2123. An apparatus for treating urinary incontinence, comprising:
| a body (400) provided with a plurality of arms (414) adapted for rendering urethral
| support for treating incontinence when inserted in a vagina;
| an arm collapser (900); and,
| a device displacer (902) coupled to the arm collapser (900) which when pulled
| causes: a) the arms (414) to collapse; and b) for providing movement to said the apparatus to
| displace.

| 2224. An apparatus according to claim 21-23 wherein said device displacer (902) is a
string.

| 2325. An apparatus according to claim 22-24 wherein said apparatus is flexible and
distorted by said string.

| 2426. A method of using an apparatus for the treatment of urinary incontinence,
comprising:

| inserting said incontinence treating apparatus (100); and,
| deploying said incontinence treating apparatus (100) in a position to render mid-
| urethral support.

| 2527. A method according to claim 24-26 wherein inserting is facilitated by an applicator
(1000).



| 445/04392 A01A02

| 2628. A method according to claims 24-26 or 25-27 further comprising removing said apparatus.

| 2729. A method according to any of claims 24-26-28 wherein said removing is facilitated by a device displacer (902).

| 2830. An apparatus (1050) for inserting an expanding and anchoring vaginal device having a preferred deployment location, comprising:

an enclosure for containing said vaginal device; and

a stopper (1058), wherein said stopper (1058) prevents over insertion and wherein said stopper (1058) is adjustably positioned on an exterior of said enclosure.

| 2931. An apparatus according to claim 28-30 further comprising a plurality of selectable positions located on said apparatus such that, upon adjustably positioning said stopper (1058) in one of said positions, insertion of said apparatus into said vagina up to said stopper (1058) will result in the apparatus being in an appropriate position within said vagina for deployment.

